REMARKS

Claims 34 to 38 remain in the application and stand rejected. Claim 34 is amended to include that the hub member is releasably attachable by the practitioner directly to and around the proximal catheter end regions (supported by paragraphs [0011] and [0036]). Claim 34 is additionally amended to state that the site is selected by the practitioner from a plurality of potential sites. To provide express support for the amendment to claim 34, the Specification is amended at paragraph [0054] regarding a plurality of potential hub sites along the length of the catheter: support is found in Figure 11 and in paragraphs [0008], [0036] and [0006] and [0007].

Claims 34 and 35 stand rejected under 35 USC 103(a) as being unpatentable over Sisley et al (U.S. Patent No. 4,405,313) in view of Raulerson (U.S. Patent No. 4,037,599) or Bierman et al (U.S. Patent No. 6,582,403). Claims 36 and 37 stand rejected under 35 USC 103(a) as being unpatentable over Sisley et al in view of Raulerson or Bierman et al and further in view of Ash et al (U.S. Patent No. 5,947,953). Claim 38 stands rejected under 35 USC 103(a) as being unpatentable over Sisley et al in view of Raulerson or Bierman et al and Ash et al in view of Cazal (U.S. Patent No. 5,800,414).

Claims 34 to 38 also stand provisionally rejected under "nonstatutory obviousness-type double patenting" in view of Serial No. 10/974,267.

Applicants respectfully request reexamination and reconsideration in view of this paper.

The hub manages the extracorporeal catheter portions by securing together the proximal lumen portions, enables the catheter assembly to be sutured to the patient for additional anchoring, and also protects the tunnel exit site against damage from any further undesirable splitting apart of the proximal lumen portions. The hub is attachable to the catheter by the practitioner at a site selected by the practitioner from a plurality of potential sites, which is advantageous compared to conventional hubs that are affixed permanently to the catheter during manufacturing at a standard site, so that the practitioner is able to modify the length of the catheter proximal end to adapt it to a particular patient where the catheter is selected by lumen size only since the hub site must be proximal of the subcutaneous tunnel exit (see paragraph [0008]). Further, the hub member is releasable from the catheter after implantation, should it become necessary to repair the catheter, without removing a damaged catheter entirely from the patient and re-implanting a new one, causing accompanying distress and risk to the patient (see paragraph [0007]). Thus, the presently

claimed invention is a greatly advantageous breakthrough in catheter implantation and repair procedures.

References Sisley et al, Ash et al and Cazal have been discussed and distinguished in previous responses. There is no support whatsoever for the assertion in the Office Action that the splitter 22 of reference Sisley is "capable/adapted to be releasably attachable to and around" the catheters ("by the practitioner" as in claim 34), and at a site selected from a plurality of potential such sites. No detail of the splitter 22 is provided other than its illustration in Figure 1 and the statement that hub 22 "wraps the junction of the tubes 12 and 14", nor when the splitter is so attached. If the Examiner has knowledge about the device disclosed in the Sisley reference beyond that which is provided in the reference itself, then Applicants respectfully request support for such information as set forth in 37 CFR §1.104(d)(2) so that Applicants can respond. Otherwise, barring such information, Applicants respectfully assert that reference Sisley makes no such teachings or suggestions to one of ordinary skill, and that rejections based on such allegations should be withdrawn on this basis. Additional basis for traversal is provided hereinbelow.

Reference Raulerson sets forth a hemodialysis catheter having two lumens where one thereof enables fluid (e.g., filtered blood) to be infused into a blood vessel of a patient, and where the other thereof permits unfiltered blood to be withdrawn from the same blood vessel at the same time in order to be filtered by a hemodialysis machine. The two lumens disclosed are coaxial, in that an outer lumen surrounds an inner lumen in the portion implanted in the blood vessel, while the proximal ends thereof may be arranged to be coupled to separate conduits of the hemodialysis machine. The coupling of the catheter lumen ends is accomplished within a hub assembly that receives the dual lumen catheter end into its distal end where the inner lumen extends deep into the hub to an end in a first channel that extends to the hub proximal end adapted to be connected to an associated machine conduit, and the outer lumen ends near the hub entrance in fluid communication with a separate second channel extending to a hub proximal end adapted to be connected to an associated machine tube end. The hub assembly includes internal seal members to seal around the catheter adjacent the distal entrance and around the extended inner lumen within the first channel. The hub assembly is disclosed to be a pair of half portions containing half channels that form whole channels when assembled about the catheter end to extend from the catheter lumen ends to the distal ends of the respective conduits, where the half portions are joined by a living hinge therealong to permit rotating into position around the catheter lumen ends in "a

closed, sealed operative relation to one another", by outwardly extending flanges along the periphery of each hub portion being "sealed together by means of an ultrasonic weld or other acceptable sealing means". (See column 3, lines 40 to 51). The hub assembly is not disclosed to be detachable from the catheter ends and is not releasable therefrom. Thus, the hub assembly is not "adapted to be releasably attachable" to proximal catheter regions that extend therethrough, and cannot be, since the hub assembly must be sealed to prevent the blood flowing in its channels between the lumen ends and the respective conduit ends from leaking. Were it desired to remove the welded and sealed hub of Raulerson from the catheter proximal ends for repositioning, the skilled artisan would expect that such removal would destroy the hub.

With respect to amended claim 34 and the grounds of rejection based on a combination of a part of Raulerson with the disclosure of Sisley et al, the artisan of routine skill would have no reasonable expectation of success in selecting a site along the catheter, since the hub of Raulerson is taught and adapted to be affixed at and to the proximal ends of the catheter, not along the proximal regions. The skilled artisan would also not expect that the hub of Raulerson would be releasable for repositioning, since the hub would be destroyed. Applicants respectfully traverse the rejection.

Reference Bierman et al sets forth an anchoring device for anchoring a catheter assembly to a patient's skin using a clampable retainer apparatus that is lockable about the catheter and unlockable therefrom. A single-lumen catheter is shown in Figure 12 and in dashed lines in Figures 3 and 4, and a dual-lumen catheter is similarly shown in Figures 27 to 29. The single-lumen catheter is shown to include a fitting (unnumbered) at its proximal end for connection to a conduit, and the double-lumen catheter 212 is shown to have a hub (unnumbered) about diverging proximal tubes whose ends are not disclosed. The retainer coacts with the unnumbered fitting or unnumbered hub of the catheter assembly, not with the catheters per se, therefore not meeting the requirement that the hub be directly attachable to the catheters. The retainer is adapted to the nature of the fitting or hub of the catheter assembly, but is itself not a hub: the retainer does not prevent two catheter tubes from further splitting distally thereof, as does the hub of the present claims, since the unnumbered hub as clearly shown provides this advantage. The retainer does not secure together the proximal end portions of the catheter's proximal tubes for management purposes, since this also is performed by the unnumbered hub. The retainer is anchored first at a location associated with the fitting or hub of the catheter assembly, whereafter the catheter

assembly is clamped thereby. There is no disclosure nor suggestion in the reference to subcutaneous tunneling of a portion of the catheter which would impact on the location of the unnumbered hub, nor is repair of a catheter proximal end addressed that would still require removal and repositioning of the unnumbered hub even if the retainer were opened to release the catheter assembly, nor that the catheter has side-by-side lumen tubes joined to each other where splitting may occur that is prevented by the hub of the present claims to preserve the tunnel exit.

Regarding claim 34 based on Sisley et al in view of Bierman et al, the artisan would understand that the anchoring system of Bierman et al is an alternative to subcutaneous tunneling, and does not provide any advantages to a catheter assembly to be subcutaneously tunneled. The combination of references set forth in the Office Action is not provided with a clear line of reasoning as to why the skilled artisan would have a reasonable expectation of success when a selected part thereof is to be combined with the disclosure of Sisley et al. While the skilled artisan may desire to use the anchoring system of Bierman et al to anchor the disclosed catheter assembly of Sisley et al, the skilled artisan would in fact find it disadvantageous to replace the hub of Sisley with the retainer of Bierman et al for reasons above stated. Applicants respectfully traverse the rejection.

The Office Action cites *In re Hutchison*, as support for holding that the phrase in claim 34 "adapted to be releasably attachable by a practitioner" carries no patentable weight. Reliance on this case is misplaced. In *In re Venezia*, 530 F.2d 956 at 959, the CCPA held that such phrases can indeed carry patentable weight: the subject claim contained the language "adapted to be affixed" and "adapted to be positioned" regarding the relationship of a pair of sleeves and a cable jacket and a pair of retaining members and the sleeves along a cable jacket, which language was held to impart a structural limitation to a sleeve, that each sleeve was so structured or dimensioned that it could be fitted over an insulating jacket of a cable, and that each retaining member was so structured or dimensioned that it could be positioned on the cable jacket to prevent the sleeves from moving toward a cable end. In the present claim, the initially separate hub member is adapted to be releasably attachable by a practitioner to and around catheter proximal end regions distally of the proximal ends such that the end regions extend proximally beyond the hub member; thus, the hub member is structured and dimensioned to both: (1) permit the catheter portions to extend completely through and beyond the hub when the hub is attachable by the practitioner to and around the catheter portions to become coupled thereto at a site selected by the practitioner,

and (2) enabling the practitioner thereafter to separate the hub portions from around the catheter proximal regions and uncouple the hub therefrom.

Claims 35 to 38 depend from claim 34, which is believed to patentably distinguish over the reference, and therefore, claims 35 to 38 are believed patentable.

Claims 34 to 38 stand rejected for "nonstatutory obviousness-type double patenting" in view of the claims of pending but later-filed continuation-in-part application Serial No. 10/974,267. The present rejection is only provisional, since the present application has a filing date earlier than the other application and once all other rejections of the present claims is overcome, the double patenting is required to be withdrawn and the present application issue. Applicants traverse the assertion in the Office Action that the claims of the other application which do not include a hub limitation, cover the present claims of a hub adapted to be releasably attachable to portions of catheter lumens distal of their proximal ends.

The claims are believed to distinguish patentably over the prior art, and allowance thereof is respectfully urged. No new limitations have been entered into the claims, and no new issues are raised. No new matter has been entered hereby. If any additional fees are due, please charge same to Deposit Account No. 50-2434.

Respectfully Submitted,

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Date

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